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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/310,844	05/12/1999	DAVID J. ECKER	IBIS-0171	9454

7590 10/22/2002

PAUL K LEGAARD
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
ONE LIBERTY PLACE 46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER	
SCHMIDT, MARY M	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/310,844	Ecker et al.
Examiner	**Art Unit**
Mary Schmidt	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 15, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *87-93 and 110-113* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *87-93 and 110-113* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 87-93 and 110-113 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 13, 14 and

16 of copending Application No. 09/310,735 for the same reasons of record set forth in the previous Official Action mailed 5/8/02. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 87-93 and 110-113 are drawn to compositions having a specific type of secondary structure found for instance in the specific nucleic acid sequences claimed (ie. SEQ ID NO:23 for instance) which would be considered one of the compositions claimed in Application 09/310,735. Application 09/310,735 claims compositions identified from a method of identifying at least one molecular interaction site on said target RNA generating in silico a virtual library of compounds predicted or calculated to interact with said molecular interaction site; and comparing three dimensional representations of said target RNA with members of the virtual library of compounds to generate a hierarchy of said compounds ranked in accordance with their respective ability to form physical interactions with said molecular interaction site. A sequence search of instant SEQ ID NO:23 identified that this sequence was disclosed in Application 09/310,735 as a composition which may be identified by the methods claimed in '735. Therefore, the instantly claimed compositions are considered to read on claims 11 and 14 of '735 drawn to compounds identified as having the ability to modulate activity of a target RNA as well as the compositions of claims 13 and 14 of '735 since the limitations "pharmaceutical, agricultural chemical or industrial chemical" are not considered to breath further life and meaning into the compositions of the instant claims having the sequences such as those claimed in the instant Application as SEQ ID NOS: 23-25, which have the claimed secondary structure. It is further noted that although a restriction has been done in

the '735 application, Applicant has elected the composition claims and the instant double patenting rejection remains valid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed July 15, 2002, have been fully considered but they are not persuasive.

Applicant traverses the rejection on pages 10 and 11 of the response. Applicant states that "[a]n obviousness-type double patenting rejection is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. 103.... Thus, under the law, the pivotal question in an obviousness-type double patenting analysis is: Does any claim in the application define merely an obvious variation of an invention disclosed ***and claimed*** in the patent?... If the answer to this question is no, there can be no double patenting." (Emphasis added by applicant)

Applicant further states that the claims of the '735 application "are drawn to compounds identified by particular methods for identifying compounds that modulate activity of target RNAs or target biomolecules. The claims of the '735 application do not recite any of the secondary structures, joined sequence length, or nucleotide sequences that are recited in the claims of the present application. Thus, the RNA molecules of the present invention, which recite secondary structures, joined sequence lengths, or nucleotide sequences are not obvious variants of the compounds claimed in the co-pending application, which fail to recite any of these elements.

That an RNA molecule of the present invention may fall within the claim scope of the co-pending application is irrelevant. In deed, a determination whether one patent application is generic to another patent application is not the appropriate inquiry." Applicants further cite case law and argue that merely "reading" on a claim, and thus providing dominance, does not "grounds for an obviousness-type double patenting rejection. It is simply a case of one patent application dominating another patent application. Domination by itself cannot support a double patenting rejection. Thus, the obviousness-type double patenting rejection is misplaced."

In response, MPEP 2112.01 states that "[w]here the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." In the instant case, the compositions of '735 are produced by the same methods as the compositions in the instant application. Since the disclosure and figures in both applications disclose the same compositions of instant SEQ ID NOS. 23-25 the structures of these compositions are included in both the structures of the instantly claimed compositions as well as the scope of compositions claimed in '735. Therefore, it is not merely a case of the broader claims in '735 dominating the instant claims, but rather, a case of *prima facie* anticipation and obviousness since the composition claims of '735 are substantially identical in structure or composition to the instantly claimed compositions.

Claim Rejections - 35 USC § 102

4. Claims 87-93 stand rejected under 35 U.S.C. 102(b) as being anticipated by McKnight et al., Immunogenetics 30, 145-147 (1989), for the same reasons of record as set forth in the Official Action mailed 10/30/01 and 05/08/02.

Applicant's arguments filed 07/15/02 have been fully considered but they are not persuasive.

In the Official Action mailed 10/30/01, the previous Examiner explained that since Mc Night et al. taught the rat interleukin-2 gene encoding RNA comprising the sequence of instant SEQ ID NO:23 and 25, the sequence taught by McNight et al. must have the same secondary sequence structure instantly claimed.

Applicant argues that it has not been established that the McNight reference contains the secondary structure recited in claim 87. In response, Applicant is referred to MPEP 2112.01 which teaches that "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...."When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."" McKnight et al. taught compositions having a sequence which reads on SEQ ID NO:23, for instance, and thus reads on the instant claims as written.

Applicant further argues the McNight reference does not anticipate every element of the claim, specifically the limitation "not more than seventy nucleotides." In response, claim 87 is

broadly drawn to any RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides...." In view of the open "comprising" language, the claim reads on sequences which are longer than 70 nucleotides and thus reads on the sequence taught by McNight et al.

5. Claims 87-93 stand rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. PNAS, vol. 82, pp. 7284-7288 (November 1995) for the same reasons of record as set forth in the Official Action mailed 10/30/01 and 05/08/02.

Applicant's arguments filed 07/15/02 have been fully considered but they are not persuasive.

In the Official Action mailed 10/30/01, the previous Examiner explained that since Chen et al. taught the gibbon and human interleukin-2 gene encoding RNA comprising the sequence of instant SEQ ID NO:24, the sequence taught by Chen et al. must have the same secondary sequence structure instantly claimed.

Applicant argues that it has not been established that the Chen reference contains the secondary structure recited in claim 87. In response, Applicant is referred to MPEP 2112.01 which teaches that "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...."When the PTO shows a sound basis for believing that the products of the applicant and the prior art are

the same, the applicant has the burden of showing that they are not.'"' Chen et al. taught compositions having a sequence which reads on SEQ ID NO:24, for instance, and thus reads on the instant claims as written.

Applicant further argues the Chen reference does not anticipate every element of the claim, specifically the limitation "not more than seventy nucleotides." In response, claim 87 is broadly drawn to any RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides...." In view of the open "comprising" language, the claim reads on sequences which are longer than 70 nucleotides and thus reads on the sequence taught by Chen et al.

6. Claims 87-91 stand rejected under 35 U.S.C. 102(e) as being anticipated by Fu et al., U.S. Patent No. 6,090,620) for the same reasons of record as set forth in the Official Action mailed 10/30/01 and 05/08/02.

Applicant's arguments filed 07/15/02 have been fully considered but they are not persuasive.

In the Official Action mailed 10/30/01, the previous Examiner explained that since Fu et al. taught the WRN gene encoding RNA comprising the sequence of instant SEQ ID NO:22 and 25, the sequence taught by Chen et al. must have the same secondary sequence structure instantly claimed.

Applicant argues that it has not been established that the Fu reference contains the secondary structure recited in claim 87. In response, Applicant is referred to MPEP 2112.01 which teaches that "where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...."When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."" Fu et al. taught compositions having a sequence which reads on SEQ ID NO:23, for instance, and thus reads on the instant claims as written.

Applicant further argues the Fu reference does not anticipate every element of the claim, specifically the limitation "not more than seventy nucleotides." In response, claim 87 is broadly drawn to any RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides...." In view of the open "comprising" language, the claim reads on sequences which are longer than 70 nucleotides and thus reads on the sequence taught by Fu et al.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 110-113 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Claims 110-113 were amended to claims purified and isolated RNA fragments up to 70 nucleotides comprising the sequence of SEQ ID NOS: 23, 24 or 25. The claims previously did not have the limitation "up to 70 nucleotides" and as such embrace useful promoter sequences.

The specification as filed teaches on pages 32, 53-155, that fragments in general are useful in the instant disclosed methods of characterizing nucleic acid interactions. However, the disclosure of instant SEQ ID NOS: 23-25 on page 152 of the specification, does not provide a specific and substantial well-established utility for these particular claimed sequences.

The definition of "specific utility" is a utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. The definition of "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A situation that requires or

constitutes carrying out further research to identify or reasonably confirm a "real world" context of use includes basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved or a method of assaying for or making a material that itself has no "specific and/or substantial utility."

In the instant case, neither the specification as filed nor the prior art teach a specific or substantial utility for a fragment up to 70 bases comprising instant SEQ ID NOS:23-25. The specification does not teach specific use of these fragments. The assertion that any fragment of any size could be used in methods of screening such as the ones disclosed in the specification as filed provides only a general utility that does not address the specific uses of fragments of 70 bases comprising instant SEQ ID NOS:23-25. Furthermore, neither the specification nor the prior art provides a "real world" use for these fragments since neither teaches that they may be useful as promoters, probes, ~~indecence,~~ antisense etc. Therefore, one skilled in the art would necessarily practice further basic research to define a "real world" context of use for any fragment up to 70 bases comprising any of instant SEQ ID NOS:23-25.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 110-113 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

M. M. Schmidt
October 17, 2002